

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

REC'D 15 JUN 2004
WIPO PCT


Applicant's or agent's file reference 112925	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/000229	International Filing Date (day/month/year) 24 February 2003	Priority Date (day/month/year) 22 February 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61F 11/04		
Applicant COCHLEAR LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 11 June 2003	Date of completion of the report 24 May 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  DAVID MELHUISE Telephone No. (02) 6283 2426

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 47 and 48

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. 47 and 48

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1 - 41, 43 - 45	YES
	Claims 42, 46, 49	NO
Inventive step (IS)	Claims 5, 7 - 34, 36, 37, 39 - 41, 44, 45	YES
	Claims 1 - 4, 6, 35, 38, 42, 43, 46, 49	NO
Industrial applicability (IA)	Claims 1 - 46, 49	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

NOVELTY (N) Claims 42, 46 and 49:

D1 - US 5443493 A

D2 - US 6070105 A

D3 - US 6125302 A

D1 discloses the features of claims 42 and 46. Figures 2 and 4 of the citation show a pre-curved electrode array 12 maintained in a straight configuration by straightening member 21. As the array is inserted into the cochlea by moving button 32 the straightening member is prevented from also moving into the cochlea as it is attached to tube 26. Therefore all features of claims 42 and 46 are disclosed by D1.

D2 discloses all the features of claim 49. Figure 2D of D2 shows an electrode array 121' for insertion into a cochlea, a straightening member 138 with a portion extending beyond the proximal end of the array and the portion including a spherical member.

D3 discloses the features of claims 42 and 46. Figures 12 and 13A show a pre-curved array 10, straightening member 62 and insertion device 64. Column 7 lines 44 to 62 describes how the straightening member 62 is progressively removed as the array is advanced into the cochlea.

INVENTIVE STEP (IS) Claims 1-4,6,35,38,42,43,46,49:

Claims 42,46 and 49: As per novelty above.

Claim 43 is not considered to involve an inventive step. D1 discloses all the features of claim 43 except for the loading cartridge. However first mounting the array into a cartridge before loading into the insertion device is not considered to involve an inventive step. I consider that this difference between the claimed invention and the citation constitutes no more than a mere workshop improvement. It is an arrangement that any competent worker in the art would be expected to make directly and without difficulty and by routine steps alone. Therefore the claimed invention does not involve an inventive step.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 40 lacks clarity because it seems as if it should be appended to claim 40 instead of 39, as claim 40 defines that the housing is angled.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

D3 renders claims 1-4, 6, 35 and 38 non-inventive. Figures 12 and 13A of D3 show an electrode array that is straightened by stylet 62. The device for implanting the array includes a main body 64. Column 7 lines 44 to 62 describe how the electrode array is simultaneously pushed off the stylet and out of the main body. While no "positioning member" is explicitly disclosed, the citation describes how a "pushing or extraction force may be applied" against shoulder 17. An instrument would be used to exert this force, this instrument being the "positioning member" of claim 1. Pushing the electrode array off the stylet would also require the stylet to be held, requiring the existence of a "capture member". Therefore the citation discloses all the features of claim 1 except that the features are not connected to form "a device". However a device that merely mimics what is done by hand is not considered to be inventive. I consider that this difference between the claimed invention and the citation constitutes no more than a mere workshop improvement. It is an arrangement that any competent worker in the art would be expected to make directly and without difficulty and by routine steps alone. Therefore the claimed invention does not involve an inventive step.